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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,730	12/24/2001	Kenji Sawa	10873.853US01	4134
7590 09/21/2004			EXAMINER	
Merchant & Gould P.C. P.O. Box 2903 Minneapolis, MN 55402-0903			MENON, KRISHNAN S	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/035,730	<b>Applicant(s)</b> SAWA, KENJI	
	<b>Examiner</b> Krishnan S Menon	<b>Art Unit</b> 1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-3 and 5-7 are pending.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sacco (US 5,059,173).

Claim 1: Sacco teaches a method of composing an infusion line comprising a spike unit (13,45) a main tube unit (12 at 27; line connecting 13, 43,40,30, etc.), an infusion filter unit (50), and a one-way valve unit (49), each unit being formed from one or more components (see figures), spike unit being at one end (see fig 1), and the distal end with respect to the spike unit having a connector for access to a patient (17).

The functional limitations, "wherein the spike unit has a function of connecting the infusion line to a supply source of a medical fluid via a spike. the main tube unit has a function of being used for adjusting a length between the spike unit and another unit positioned on a patient side, the injection device unit has a function of being used for injecting the medical fluid or collecting blood. the infusion filter unit has a function of being used for removing foreign substances- and the one-wav valve unit has a function of preventing a back flow of an infusion fluid", and "... a connector *capable of* being used for a connection to a member to access a patient" are inherent. Under the

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principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986)

Sacco does not specifically state the method as 'determining a composition' of an infusion line. However, it would be obvious to one of ordinary skill in the art at the time of invention that Sacco having made an infusion line for the process of infusion would have to first determine the composition needed in the infusion line before building the infusion line. Regarding the 'combination of components having specified shapes and sizes so that a single size connector is capable of connecting the plural kinds of units together', changes of size, shape, etc without special functional significance are not patentable. Research Corp. v. Nasco Industries, Inc., 501 F2d 358; 182 USPQ 449 (CA 7), cert. denied 184 USPQ 193; 43 USLW 3359 (1974). Sacco teaches this combination of components of specific sizes and shapes (though such specific wording is not used) in col 1 line 42- col 3 line 10, especially col 1 lines 42-59 and col 2 lines 52-67.

There is an extension tube as in claim 2 and 3, distal to the spike unit (12 at 17). Function of the extension tube is inherent – In re King. Spike unit is connecting the infusion line to a supply source (14), main tube unit adjusts the length between the

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spike unit and other units positioned in the patient side (see fig 1), injection device (53) is positioned between the main tube unit and the extension tube and could be used for injecting medicines, infusion filter is positioned between the main tube unit and the extension tube (see 40), one-way valve is positioned on the opposite side of the spike unit with respect to the main tube unit to prevent back flow of infusion fluid (49), all as in claim 4. Claim 5 recites the relative positions of the various units and further adds the limitation of the extension tube positioned on the patient side allowing the infusion line to be held at hand of the patient (see fig).

Re the limitation of 'determined to be included' in the instant claims, it would be obvious to one of ordinary skill in the art at the time of invention that Sacco having made an infusion line for the process of infusion would have to first determine the composition needed in the infusion line before building the infusion line.

2. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urquhart et al (US 4,552,556)

Urquhart teaches a method of composing an infusion line comprising a spike unit (52-fig 2), a main tube unit (54) and an infusion filter unit (58; 142-fig 13; col 14 lines 13-31) as in claim 1. The method further comprises composing an extension tube to the end on the distal side with respect to the main tube unit as in claims 2 and 3 (23-fig 2). Urquhart does not specifically state the method as 'determining a composition' of an infusion line or unit groups 'determined to be included'. However, it would be obvious to one of ordinary skill in the art at the time of invention that Urquhart having made an

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infusion line for the process of infusion would have to first determine the composition needed in the infusion line before building the infusion line. Regarding the 'standardized shapes and sizes so that a single size connector is capable of connecting the plural kinds of units together', changes of size, shape, etc without special functional significance are not patentable. *Research Corp. v. Nasco Industries, Inc.*, 501 F2d 358; 182 USPQ 449 (CA 7), cert. denied 184 USPQ 193; 43 USLW 3359 (1974).

The functions of each unit or unit group are inherent – *In re King*.

3. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sacco (173) in view of Urquhart et al (US4,552,556).

Sacco teaches all the limitations of claims 1 and 2. Claims 6 and 7 add further limitations of spike unit including a spike and a drip chamber, which Sacco does not teach. [Sacco has the spike drip chamber down-stream of the filter, away from the spike unit]. Urquhart teaches a spike unit having a spike and a drip chamber (see 15-17, fig 1, and col 4 lines 65-68). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Urquhart in the teaching of Sacco to have the spike and the drip chamber together so that the drip chamber can be used to trap air in addition to adjust the flow rate, as taught by Urquhart. Additional limitations of claims 6 and 7 as taught by Sacco are: main tube having a clamp and connector (line 12 or 25 at 50), injection device including a connector and an injection port (52), infusion filter has a filter, tube and connector (40), one-way valve unit has a valve and a connector (49), extension tube has a tube and a connector (12 at 17). Re the newly added limitation of 'determining the composition', it would be obvious to one of ordinary skill in

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the art at the time of invention that Sacco in view of Urquhart having made an infusion line for the process of infusion would have to first determine the composition needed in the infusion line before building the infusion line.

### ***Response to Arguments***

Applicant's arguments filed 7/22/04 have been fully considered but they are not persuasive.

Applicant's arguments have the basis that the references do not 'teach or suggest a method of determining the composition of an infusion line'. In response, the references have *at least* put together an intravenous line to administer fluids to a patient, and to put a line together requires determining the composition of the infusion line. In addition, Sacco does contemplate such a 'method of determining' (even if the specific terminology is not used) in col 1 line 42 – col 3 line 10. Applicant's argument of 'defining the classification of units based on function' is not patentable, unless the applicant can show with evidence that such a method is unanticipated and unobvious over the references.

### ***Conclusion***

This action is in response to an RCE, and is made non-final because a 'new issue requiring new consideration' was indicated in the prior advisory action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krishnan Menon  
Patent Examiner

  
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